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EXAMINER

LEA, CHRISTOPHER RAYMOND

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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08/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/587,729	Applicant(s) VELDHUIZEN ET AL.	
	Examiner Christopher R. Lea	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/8/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 (national stage application) of PCT/EP05/00117.

Receipt of Amendments/Remarks filed on May 4, 2009, is acknowledged. In response to Non-final office action dated February 4, 2009, applicant amended claims 1, 6, 7, & 13 and added new claims 20 & 21. Claims 1-21 are pending. Claims 1-21 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

1. The information disclosure statement(s) (IDS) submitted on May 8, 2009, was filed after the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claim 3, it is unclear what is meant by “discrete regions.” Two separate layers of fatty matter in the matrix would be in discrete regions but not dispersed, thereby rendering the claim internally inconsistent. Therefore, it is unclear at what size or volume the discrete regions become dispersed, hence the metes and bounds of this claim are untenable. Further, it is unclear what applicant considers to be a discrete region, as the specification appears to contain contradictory indications of what constitutes a discrete region. At lines 32-34 of page 4 in the specification (paragraph 15 in the published application) the applicant appears to set out droplets, crystals, and particles as species of discrete regions. However, at line 20 on page 7 (paragraph 25), applicant appears to set out droplets, crystals and particles as alternatives to discrete regions.

Contrary to applicant's assertion that a skilled artisan could well ascertain whether the material is dispersed as discrete regions, the examiner believes that this term and its conflicting disclosure in the specification would not allow one of ordinary skill in the art to reasonably ascertain the metes and bounds of the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3-11, 17, 18, & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlsten et al. (WO 00/33669, cited by applicants on IDS).

Applicant claims

Applicant claims particulates that contain a fatty material comprising phytosterol in a matrix material comprising a protein and a carbohydrate. Applicant further claims food product compositions containing said particulates and a method of making the particulates.

**Determination of the scope and content of the prior art
(MPEP 2141.01)**

Dahlsten et al. teach, as a whole, food products containing phytosterols.

Claim 1: Dahlsten et al. teach particulates containing milk (a matrix material containing both a carbohydrate, lactose, and a protein, casein) and sitosterol (a phytosterol) (examples 10 & 11, p. 10).

Claims 3 & 4: Dahlsten et al. teach that the phytosterol are present in liposome particles in the matrix (examples 10 & 11, p. 10) which are discrete regions.

Claim 5: Dahlsten et al. teach milk as a matrix material, which necessarily contains dairy protein (examples 10 & 11, p. 10).

Claim 6: Dahlsten et al. teach milk as a matrix material, which necessarily contains the sugar lactose (examples 10 & 11, p. 10). Also, Dahlsten et al. teach a chocolate milk composition which contains 8% sugar (example 11a, p. 10)

Claims 7 & 21: Dahlsten et al. teach milk as a matrix material (examples 10 & 11, p. 10). The genus of milk types is so small and each member so similar that one immediately envisages skim milk from a teaching of milk.

Claims 8 & 9: Dahlsten et al. teach liposome particles sizes of 1.3-5 μm (examples 10 & 11, p. 10).

Claim 10: Dahlsten et al. teach freeze-drying the composition (example 10, p. 10) which necessarily involves reducing the water content to below 5%.

Claim 11: Dahlsten et al. teach using the phytosterol liposomes in cream powder (whitener) (claim 14).

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Claims 17 & 18: Dahlsten et al. teach preparing the particulates by emulsifying the matrix and fatty materials in an aqueous liquid, followed by homogenizing the emulsion (examples 1-3 & 11, p. 6-8 & 10), before drying the emulsion (example 11, p. 10).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the teachings of Dahlsten et al. and the instant claims is that Dahlsten et al. do not specifically embody the claimed percent composition of the invention.

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to vary the component percentages in the particulate composition taught by Dahlsten et al. and produce the instant invention. The skilled artisan would have been motivated to vary the component percentages because the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. It is within the purview of the skilled artisan to discover the workable and optimum ranges through routine experimentation where the general conditions are known, and absent some evidence of the criticality of the claimed range, a difference in concentration will not support patentability.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in varying the percentages of the components and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claims 2, 11-16, 19, & 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlsten et al. as applied to claim 1 above, and further in view of Goulson et al. (US PreGrant Publication 2004/0013708).

Applicant claims

Applicant claims food products containing phytosterol esters.

Determination of the scope and content of the prior art (MPEP 2141.01)

Since claims 2, 11-16, 19, & 20 depend from claim 1, rejection of claim 1 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 1 and the teachings of Dahlsten et al. appears above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

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The difference between the teachings of Dahlsten et al. and the instant claims is that Dahlsten et al. fails to teach the claimed food products containing phytosterol particulates. This deficiency in Dahlsten et al. is cured by the teachings of Goulson et al.

Goulson et al. teach, as a whole, food products containing phytosterol esters (Goulson uses the collective term “steryl esters” for fatty acid esters of phytosterols, see paragraph 24).

Claim 2: Goulson et al. teach incorporating steryl esters into oil-in-emulsions for use in food products and pre-mixes (particulates) (paragraph 22).

Claim 11, 12, 14, & 19: Goulson et al. teach using the steryl esters in a variety of food products, such as whiteners, soups, sauces, and their pre-mixes (paragraph 49). The process claimed in claim 19 would necessarily be accomplished through the preparation of the composition claimed in claim 14.

Claims 13 & 20: Goulson et al. teach a composition containing 0.5% salt and 29% steryl esters (example 6 in paragraph 84, note all other claimed components are optional since the composition may contain 0% of them).

Claim 15: Goulson et al. teach a composition containing 1.5% instant coffee and 29% steryl esters (example 6 in paragraph 84).

Claim 16: Goulson et al. teach a composition containing 0.5% flavor, 56% sugar, and 29% steryl esters (example 6 in paragraph 84). Goulson et al. teach adding the creamer composition to tea (paragraph 49), hence it would have been obvious to use tea as the flavor in drink mix, and it would have been further obvious to use black tea as

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it is an immediately envisaged species from the genus of teas (black, green, oolong, and white teas).

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate the food products taught by Goulson et al. using the particulates taught by Dahlsten et al. and produce the instant invention. The skilled artisan would have been motivated to use the particulates in the food products because Dahlsten et al. teach that the liposome particulates are easier to produce than the phytosterol esters, are more soluble than crystalline phytosterols, and are more easily absorbed in the intestine than either phytosterols or their esters (p. 3, line 9 through p. 4 line 26).

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in incorporating the liposomal phytosterol particulates of Dahlsten et al. into the food-products of Goulson et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

9. Applicant's arguments filed May 4, 2009, have been fully considered but they are not persuasive. Applicant argues that 1) Dahlsten et al. do not teach the claimed critical range of fatty matter and 2) that Goulson et al. are silent as to the fat being dispersed in a matrix.

As to 1) the examiner acknowledges that the Dahlsten et al. does not teach the claimed ranges; however the examiner notes that it is within the purview of the skilled artisan to discover the workable and optimum ranges through routine experimentation where the general conditions are known, and, in the absence some evidence of the criticality of the claimed range, a difference in concentration will not generally support patentability (MPEP § 2144.05 II). Additionally, the argument of counsel cannot take the place of evidence in the record when evidence is necessary to rebut a *prima facie* case of obviousness (MPEP § 2145 I).

As to 2) in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's assertion that Goulson et al. are silent concerning the dispersion of the fatty material, while correct, is irrelevant. As Dahlsten et al. has shown this element and the rejections involving Goulson et al. are necessarily combined with Dahlsten et al., the combination of the references still teaches all the claimed elements.

For all these reasons the rejections under 35 U.S.C. § 103(a) are maintained.

Conclusion

Claims 1-21 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Fri 8:00-4:30 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Ernst V Arnold/
Primary Examiner, Art Unit 1616